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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,570

11/09/2005

Sakae Sato

8062-1029

1832

466

7590

12/02/2008

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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

12/02/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,570	<b>Applicant(s)</b> SATO ET AL.	
	<b>Examiner</b> Sandra Saucier	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-15 and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-15 and 17-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/4/08, 9/3/08</u> .                                          | 6) <input type="checkbox"/> Other: _____                          |

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#### DETAILED ACTION

Claims 12-30 are pending. Claims 12-27, 29, 30 are considered on the merits. Claim 28 is withdrawn from consideration as being drawn to a non-elected invention.

#### ***Information Disclosure Statement***

#### ***Claim Rejections – 35 USC § 112***

##### INDEFINITE

Claim remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

##### SCOPE of ENABLEMENT

Claims 12, 13, 17, 18, 20-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for processing fresh plasma, does not reasonably provide enablement for processing frozen plasma. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The examples are directed to the filter processing of fresh plasma.

Burnouf et al. disclose that processing frozen plasma by the instant method leads to rapid clogging of the filter membrane (page 116, Discussion).

The claims admit the processing of both fresh and frozen plasma.

Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and limited number of working examples in the

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specification, the nature of the invention, the state of the prior art, breadth of the claims and the unpredictability of the art.

***Response to Arguments***

Applicant's arguments filed 9/3/08 have been fully considered but they are not persuasive.

Applicants argue that although fresh plasma is preferable...the freeze itself does not cause a reduction in permeability. The argument is not understood in light of the cited reference which teaches that processing frozen plasma leads to rapid clogging of the filter membrane. Since this is merely argument of counsel without supporting evidence contrary to teachings in the art, the argument is unpersuasive of error in the formulation of the rejection.

***Claim Rejections – 35 USC § 103***

Claims 12–16, 18–26, 29, 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over JP 64–051075 [IDS].

The claims are directed to a method for producing a plasma or serum product comprising:

separating plasma from whole blood, reducing leukocytes in the plasma, filtering the plasma with a virus removing membrane.

The reference is relied upon as explained below.

JP 64–051075 discloses a method of treating blood comprising filtering the blood through a leukocyte filter, separating the plasma, passing the plasma through a virus removing membrane.

Although the order of the steps is not the same, i.e. the blood which includes plasma/serum is leukoreduced prior to the separation of red cells,

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platelets, i.e. producing the plasma, in the absence of evidence of criticality, a change in the order of steps is *prima facie* obvious, see MPEP 2144.04 IV. C.

With regard to the ranges of the size of the pores of the filter, this is considered to be an optimization well within the purview of one of ordinary skill in the art in the absence of evidence to the contrary. See MPEP 2144.05 I.II.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 64-051075 as applied to claims 12-16, 18-26, 29, 30 above, and further in view of JP 3-146067 [IDS].

The claims are further directed to the use of two virus reduction filters of decreasing pore size in tandem.

JP 03-146067 discloses the use of virus removal filter membranes in tandem and in decreasing pore size in order to maintain a high filtration rate.

The substitution of two virus removal membranes with decreasing pore sizes for the single virus removal membrane in the disclosure of JP 64-051075 would have been obvious when taken with JP 03-146067 for the advantages disclosed by JP '067.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions/additions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

### ***Response to Arguments***

Applicants argue that unexpected results are obtained when using the order of steps in their claimed method. This is evidence of criticality of the order of the steps. However, the leukocyte reduction step is not commensurate

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in scope with the showing of unexpected results or criticality as demonstrated by example 1 and comparative example 2 because it is not a filtration step. Also, the exemplifications which show the unexpected results incorporate a 75nm prefiltration and 35nm virus filtration steps, which are also not present in the claimed method.

JP 64-051075 states in the examples that 3 liters of blood was processed using the setup of Figure 1. This does not appear to show that the order of steps interferes with a virus filtration operation. Thus, the arguments and showing are not commensurate in scope with the claimed method.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

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Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/  
Primary Examiner  
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